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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,091	04/30/2001	Joel R. Haynes	APF 40.01	3986

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/846,091	HAYNES ET AL.	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,21-23,26,28,29,33-45,47,49 and 50* is/are pending in the application.

4a) Of the above claim(s) *26,28,29,33-45,47,49 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I and SEQ ID NO: 1 in the reply filed on June 9, 2004 is acknowledged.

Claims 26, 28, 29, 33-45, 47, 49 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 9, 2004.

Information Disclosure Statement

The information disclosure statement filed on March 24, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because legible copies for each foreign patent document and non-patent literature document were not provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a). However, the US Patent references have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7 and 9-14, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Webster R. (US 5,916,879).

The instant invention is drawn to a polynucleotide vaccine comprising an antigen. The vaccine composition contains the nucleic acid sequence that encodes an influenza virus M2 antigen in addition to another influenza viral antigen (NP, NA, HA, PB1, PB2, PA, M1, M2, NS1, and NS2), which are both present in a plasmid and coated onto a core carrier particle. The adjuvants of the instant invention could be a nucleic acid sequence that encodes a polypeptide, a polypeptide, a lipid (fats, etc.), a vitamin (i.e. nutritional supplement), a non-protein hormone (steroid), a saponin (i.e. Quil-A), or an analog thereof.

Webster teaches the development of a DNA polynucleotide vaccine comprising influenza antigens in plasmids that are coated on gold particles in combination with adjuvants. The antigens disclosed by Webster are PB2, PB1, PA, a NS protein, NP, N1, M2 and HA. The plasmids used by Webster could encode one or more influenza antigens. The pharmaceutically acceptable adjuvants disclosed by Webster were immuno-effector compounds such as cytokines, fats, squalines (a nutritional supplement from fish oil and is considered a precursor of steroids), iscoms (which saponin is a component of) or the adjuvant can be encoded by a sequence in the plasmid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster R. as applied to claims 1-3, 5-7 and 9-14, 16 and 17 above, and further in view of Davis et al. (Journal of Immunology, 1998), Dulbecco R. (Encyclopedia of Human Biology 2nd Ed., 1997) and Lindstrom et al. (Journal of Virology, 1998).

The instant invention as stated above is drawn to a polynucleotide vaccine comprising encoded influenza antigens in a plasmid coated onto a core carrier particle with an adjuvant such as those stated above or a CpG sequence. In addition, the M2 polypeptide encoded by the nucleic acid of the instant invention comprises an amino acid sequence of SEQ ID NO:1 and hybrids or combinations thereof.

As stated above, Webster teaches the use of pharmaceutically acceptable adjuvants with the disclosed polynucleotide vaccine. However, Webster does not specifically disclose CpG sequences or monophosphoryl lipid A or SEQ ID NO:1 as the M2 polypeptide sequence.

Davis et al. teach the use of CpG sequences as an effective adjuvant when combined with a Hepatitis B vaccine in mice.

Dulbecco discloses the several well-known adjuvants currently utilized in vaccines. For example monophosphoryl lipid A.

Lindstrom et al. teach the sequence analysis of six different internal genes of Influenza A (H3N2) viruses isolated between 1993 and 1997. The internal genes were PB2, PB1, PA, HA, NP, NA, M and NS. Lindstrom et al. disclose the accession numbers U65569 and U65574, each of which are 97 amino acids long and contain the elected amino acid sequence of SEQ ID NO:1 between residue 1 and 24 of the above accessioned sequences.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Webster in order to develop an influenza polynucleic acid vaccine with a pharmaceutically acceptable adjuvant. One would have been motivated to do so, given the suggestion by Webster that the any pharmaceutically acceptable adjuvant can be used. There would have been a reasonable expectation of success, given the knowledge that CpG sequences and monophosphoryl lipid A are effective adjuvants, as taught by Davis et al. and Dulbecco, and also given the knowledge that an amino acid sequence comprising SEQ ID NO:1 has been isolated, as taught by Lindstrom et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21-23 are indefinite because they depend on claims that have been canceled. Therefore, it is unclear as to what claim the above claims are dependent on and subsequently further limit.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Benjamin Blumel
Patent Examiner

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